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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/606,909	06/29/2000	Ronald J. Pettis	P-4901	7814

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EXAMINER	
HAYES, MICHAEL J	

ART UNIT	PAPER NUMBER
3767	

DATE MAILED: 02/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/606,909	PETTIS ET AL.	
	Examiner	Art Unit	
	Michael J. Hayes	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 October 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-7,10-24,29 and 32-39* is/are pending in the application.

4a) Of the above claim(s) *17-24 and 32-39* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-7,10-16 and 29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 June 2000* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Newly submitted claims 32-39 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the newly submitted species include method of treatment of toxicity, controlling thrombosis, and controlling infection; and various drugs as antitoxin, pain controllers, opioids, analgesics, anesthetics, heparin, coumadin, warfarin, and antibiotics. Prosecution has been developed concerning the methods of delivering a hormone, such as PTH or insulin.

Since applicant has received an action on the merits for the previously presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 32-39 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 2-7, 10-24, 29, and 32-39 are pending. Claims 17-24 and 32-39 are withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 29, 2-5, and 10-16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application

was filed, had possession of the claimed invention. The specification as originally filed did not describe the subject matter now claimed in claims 29, 2-5, 10-16. The originally filed specification did not describe a method of administering a drug to a human with applying pressure to effectively control the rate of delivery so that the drug is delivered into the intradermal (ID) compartment to exhibit a pharmacokinetic profile similar to subcutaneous (SC) delivery, but with higher maximum plasma concentration and a higher bioavailability.

In the originally filed specification difference in bioavailability between ID and SC administration was not explicitly discussed, rather Applicant has made several statements regarding the similarity of ID and SC injections. In the specification, pg. 3, ll. 9-15 Applicant discusses how the ID method shows "very similar" pharmacokinetics with SC delivery, with the only mentioned difference as "reduction or elimination of pain for the patient." Additionally, Applicant makes other statements that the ID method is considered the same as SC delivery, (See original specification: pg. 3, line 35 - pg. 4, line 1; pg. 7, ll. 11-12; and pg. 8, ll. 13-15) except for resulting pain.

The only mention of another difference with ID delivery over SC delivery is that ID delivery "often provides higher plasma levels of drug than conventional SC administration." There is no mention of maximum drug concentration (Cmax) and/or a higher bioavailability. Even here, Applicant does not state how to achieve the higher plasma levels with certainty, rather only a statement that it occurs often, and limits statement to drugs that are susceptible to *in vivo* degradation or clearance. (pg. 6, ll. 2-6).

Even the working examples and figures do not support the claimed invention of higher Cmax and higher bioavailability. In the working examples with insulin Applicant

states that ID and SC show "similar plasma insulin levels and onset periods." (pg. 7, ll. 11-12) and that drops in glucose with ID delivery of insulin were similar to those seen in SC delivery (pg. 8, ll. 13-15). The figures do not describe much more than these statements. The statistical error shown in figs. 1 and 4 are inconclusive concerning the values of Cmax for ID and SC delivery. Also the bioavailability cannot be determined from the data shown in the figures because the Cmax is inconclusive and the area under the curve (AUC) are not represented as they would need to be shown to be conclusive for bioavailability measurements.

Applicant's submitted prior art document The Merck Manual of Diagnosis and Therapy (17^{th} ed.) (1999) describes various methods to calculate bioavailability, depending on Cmax, (time at which maximum concentration occurs), Tmax, and AUC (pg. 2560, Assessment of Bioavailability). Here the manual states that to accurately measure AUC samples must be taken frequently over a long enough time "to observe virtually complete drug elimination." (pg. 2560). Applicant's fig. 3 does not show measurement to virtual elimination of the drug and therefore are inconclusive to AUC between ID and SC.

In view of the evidence discussed above, the originally filed description does not support claims for a method of ID delivery to achieve higher maximum plasma concentration and higher bioavailability over that achieved with SC delivery.

Claims 29, 2-5, 10-16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for merely delivering insulin and PTH to an intradermal layer in swine, does not reasonably provide enablement for delivery of all drugs at pressure ranges to achieve a method of ID delivery with higher maximum

plasma concentration and higher bioavailability over these achieved with SC delivery to a human subject. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. Applicant's disclosure does not support a claim dominating every drug and its delivery into a intradermal compartment of a human subject. There is a lack of reasonable correlation between the disclosure and the broad scope of protection of the claims. Because of breadth of the claims, level of predictability in the art and direction provided by the invention, scarcity of working examples, and quantity of experimentation required to use the claimed method, these claims are rejected as not being enabled.

The experimentation is considered undue because biologic system have well recognized unpredictability, particularly with respect to drug effects on individuals, a large number of experiments are required to find the correct parameters to achieve the claimed method though the experimental methods are well known, and the lack of guidance in the specification. At most the specification merely invite one of ordinary skill in the art to experiment with various drugs to see if the particular drug will show increased Cmax and bioavailability in human subjects.

Applicant's statement that experiments using various pressures combined with blood tests over a period of time (Applicant's data show approximately 6 hrs of experimentation per pressure value would be expected) along with various delivery sites on a patient's skin and repeating the same conditions except with subcutaneous injection would be required for each drug desired to be used in the claimed method. This would result in a very large number of experiments that would require an inordinate amount of

time. Applicant provides guidance for one example with insulin and one example with PTH. This narrow disclosure is insufficient to support a method of delivering all drugs, at all pressures/flow rates, for all patients.

Applicant's specification at page 7, lines 21-23 acknowledges that the data demonstrates the method's efficacy for hormone drugs and "indicates that ID infusion may actually provide higher plasma levels for drugs that are susceptible to in vivo biological degradation or clearance." (emphasis added). Additionally, Applicant states that the data merely shows a "strong probability" of successful pharmacological results for ID delivery. (specification, pg. 8, ll. 19-21). Applicant's own uncertainty with respect to the method's efficacy for other drugs shows the unpredictability of the disclosed method.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 29, 2-7, and 10-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over GROSS in view of GANDERTON and/or AUTRET, PURI (*An investigation of the intradermal route as an effective means of immunization for microparticulate vaccine delivery systems*), D'Antonio et al. (US Patent No. 6,056,716), and SRIVASTAVA (US Patent No. 6,007,821) and The Merck Manual of Diagnosis and Therapy (17th ed.) (1999).

Gross discloses a method of delivering insulin and hormones intradermally (3:40-41; 6:56 - 7:20) using a single needle with an outlet at a depth of 250 μm - 2mm in a controlled manner based on needle diameter (4:10-35). The plasma profile would be inherently similar to, but higher as compared to subcutaneous injection. Because Applicant argues that the needle length and enough pressure to control delivery are the essential limitations required to achieve the claimed method these limitations found in Gross would inherently allow the method disclosed in Gross to achieve a higher Cmax and bioavailability as compared to subcutaneous injection. Gross does not disclose a needle with exposed height of 0 - 1mm. Ganderton discloses injecting a substance through multiple needles with a zero exposed height (2:37-55) with an outlet at 1000 μm (2:55-60). See fig. 1. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Ganderton in the method of Gross in order to provide a known flow dynamic as desired from the end of the delivery needle. The zero exposed height needle as disclosed in Ganderton would be known to provide a longitudinally directed flow instead of a radially directed flow when exiting the needle opening.

If the claimed method of intradermal delivery disclosed by Gross is not inherent it would have been obvious to one of ordinary skill in the art to deliver drugs at particular pressures and flow rates to achieve higher Cmax and bioavailability with intradermal injection as compared to subcutaneous injection. Autret, Puri, D'Antonio, and Srivastava each suggest a greater Cmax and bioavailability that intradermal injections give as compared to subcutaneous injections (see Puri, pgs. 2609-2610, D'Antonio col. 29, lines 3-9, and Srivastava col. 19, line 60 - col. 20, line 25). Autret discloses intradermal

injection of a hormone resulting in pharmacokinetic profile similar to subcutaneous delivery, but with a higher plasma level and bioavailability as assessed by Cmax and Tmax (See fig. 1). The Merck Manual is used to show the various methods that bioavailability is assessed (see pg. 2560). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Autret, Puri, D'Antonio, or Srivastava in the method of Gross and Ganderton in order to more effectively treat patients and save drug costs.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 29, 2-7, and 10-16 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 8 and 10 of

copending Application No. 10/868482; claims 1, 2, 7, 8, 50 of copending Application No. 10/867908; claims 1-7, 9, 13, 16, 26, 28-30, 32, 35-41, 46-48, 50, 52-54, 57, 59, and 62-64 of copending Application No. 10/487485; claim 25 of copending Application No. 11/004780; claim 25 of copending Application No. 11/004778; claims 1-3, 8, 10-16 of copending Application No. 10/841992; claims 1-6, 11-16, 18 of copending Application No. 10/803735; claims 22-26, 29-31, 33 of copending Application No. 10/650039; claim 33 of copending Application No. 10/429973; claims 65, 71, 72, 75-77, 82 of copending Application No. 09/893746; claims 31, 32, 36, 37, 39, 49, 67, 73 of copending Application No. 10/028988; and claims 69, 72, 83-86, 88, 90, 100, 103 of copending Application No. 10/028989 alone or in view of Gross, Ganderton, Autret, and/or Srivastava. The claims in the present application and the claims of the listed pending applications recite the delivery of drugs to the intradermal compartment to achieve greater absorption, Cmax, and/or bioavailability. Gross teaches a method of delivering insulin and hormones intradermally (3:40-41; 6:56 - 7:20) using a single needle with an outlet at a depth of 250 μm - 2mm in a controlled manner based on needle diameter (4:10-35). Ganderton teaches injecting a substance through multiple needles with a zero exposed height (2:37-55) with an outlet at 1000 μm (2:55-60). See fig. 1. Autret, Puri, D'Antonio, and Srivastava each suggest a greater Cmax and bioavailability that intradermal injections give as compared to subcutaneous injections (see Puri, pgs. 2609-2610, D'Antonio col. 29, lines 3-9, and Srivastava col. 19, line 60 - col. 20, line 25). Autret discloses intradermal injection of a hormone resulting in pharmacokinetic profile similar to subcutaneous delivery, but with a higher plasma level and bioavailability as assessed by Cmax and Tmax (See fig. 1). It would have been obvious to one of ordinary

skill in the art at the time of the invention to use the teachings of Autret, Puri, D'Antonio, Srivastava, Gross and/or Ganderton in the method of Application Nos. 10/868482, 10/867908, 10/487485, 11/004780, 11/004778, 10/841992, 10/803735, 10/650039, 10/429973, 09/893746, 10/028988, and 10/028989 in order to provide a known flow dynamic as desired from the end of delivery needles to provide a longitudinally directed flow and to more effectively treat patients with lower drug costs resulting from using less drugs dosages.

These are provisional obviousness-type double patenting rejections.

Response to Declarations and Arguments

The declarations submitted by Dr. Pettis (one of the inventors in present application) and Dr. Kasting (no disclosed relationship to named inventors of present application) under 37 CFR 1.132, filed 10/7/05, are insufficient to overcome the rejection of claims 29, 2-7, and 10-16 based upon insufficiency of disclosure under 35 U.S.C. 112, first paragraph and/or insufficiency of rejections under 35 USC 103 as set forth in the last Office action because of the lack of sufficient facts to overcome the rejections, some facts not germane to rejections at issue, and showings not commensurate in scope with the claimed method.

Kasting's statements in 9, 10, 11, are concerned merely with intradermal delivery. These statements are not commensurate in scope with the claimed method, regarding delivery of drugs intradermally with higher maximum plasma concentration and bioavailability than subcutaneous delivery. Kasting's statements at 12 and 13 do not supply specific data as evidence, but rather relies on opinion. Statements regarding

amount of experimentation address merely one factor that is used to determine if the experimentation is undue. Kasting's statements at 16 show that the present application merely is an invitation to find drugs that show the claimed features. Delivery to the intradermal compartment is known and there is no data presented that show delivery rates for various drugs to achieve the claimed method.

Kasting's statements regarding the prior art do not supply facts to overcome the prior art of record, and are specifically characterized by declarant as his opinion. See statements at 17.

Pettis declaration regarding whether intradermal delivery inherently results in higher Cmax and AUC is not commensurate with the scope of the claims addressing higher maximum plasma concentrations and bioavailability of drugs delivered intradermally. The breadth of the claims is larger than the scope addressed by declarant. The data presented in Tables 2 and 3 actually show higher bioavailability as assessed by Cmax and Tmax with ID delivery as compared to SC delivery. Applicant has not defined bioavailability as only assessed by AUC.

Some of Applicant's arguments do not apply because of the new rejections as discussed above. As some issues remain and are pertinent to Applicant's arguments submitted 10/7/05 they are addressed below.

Applicant states that Autret does not recognize higher maximum plasma concentration and bioavailability. The examiner disagrees because the data presented by Autret shows a higher Cmax and a higher bioavailability as assessed by Cmax and Tmax (See fig. 1). The difference in Autret's recognition and Applicant's of their own data appears to be based on differing statistical analysis; however Applicant has not claimed

any results with respect to a particular statistical significance. Applicant states the Autret does not recognize any difference between ID and SC deliveries. The examiner notes that in view of the document as a whole, Autret's statements concerning no difference are directed to no "significant" differences and that the figures clearly show a difference. The statistical analysis applied to the experimental data appears to determine what is a significant difference and Applicant has not claimed the difference between ID and SC to be different with respect to a particular statistical analysis.

Applicant's arguments regarding the prior art not showing both higher Cmax and higher AUC are not convincing because Applicant is arguing limitations that are not recited in the claims or are not the same scope of the claims. The claims recite an ID delivery method giving higher maximum plasma concentration and higher bioavailability, not AUC. The Merck Manual (cited above) states that there are several methods to assess bioavailability, particularly Cmax, Tmax, and AUC. Applicant's specification has not explicitly defined that bioavailability is calculated only by AUC in his invention. Using Cmax and Tmax Autret is seen to show higher bioavailability with ID delivery than SC delivery.

The role of pressure is not consistent in Applicant's arguments. Pressure is acknowledged as a critical feature in the first paragraph on pg. 7 of remarks received 1/06/05, but then Applicant states "Nor is the absolute value at which pressure is applied critical to the claimed invention." (3rd paragraph of remarks received 1/06/05). Since pressure values determine the flow rate it appears from the specification that it is a critical feature of the claimed method. Applicant's remarks submitted 10/7/05 address the critical and non-critical nature of pressure in his method, but these remarks do not

further clarify the issue. Applicant's remarks that application of the correct amount of pressure is critical, but the absolute value of the pressure used is not critical are inconsistent. The absolute value of pressure used is the amount of pressure applied, and since both concern the pressure applied, either both are critical or not. Furthermore, Applicant's disclosure does not provide any guidance at which pressures are required to achieve the claimed method. Applicant merely invites the skilled artisan to experiment to determine pressure on their own.

Applicant has not showed any data to support their statement that ID delivery would not inherently result in a higher Cmax and bioavailability, and therefore have not met their burden in arguing against inherency. Applicant arguments submitted 1/06/05, concerning avoiding leakage or excessive weal formation at the skin surface does not apply to delivering to the intradermal compartment. Delivery to the intradermal compartment requires that the drug is delivered to this volume, not that some leaks at the skin surface. Therefore it appears that when a drug is delivered to the intradermal compartment it inherently results in a higher Cmax and bioavailability. Applicant's data submitted 10/7/05 with Pettis declaration also show improved Cmax and bioavailability as assessed by Cmax and Tmax. See also discussion above of Pettis declaration submitted 10/7/05.

The Pettis declaration submitted 1/06/05 under 37 CFR 1.132 has been considered, but does not provide data or facts sufficient to withdraw the present rejections. There is no data or facts presented that show delivery to the intradermal compartment does not inherently result in higher Cmax and AUC. The discussed fact that pressure is applied to deliver drugs (disclosed in the specification) to the intradermal

compartment to give higher Cmax and AUC does not refute the inherency rejection. Showing only data where the desired result was achieved does not meet Applicant's burden that the results are not inherent.

Applicant arguments that Puri and D'Antonio are concerned with vaccines, not drugs are not convincing. Applicant has not explicitly defined drugs in the specification to include or exclude various compounds. Applicant argues that D'Antonio is not concerned with injection of drugs or ID delivery, but focuses on intramuscular injections. This position is not convincing because although D'Antonio discusses intramuscular injections, the benefits of ID delivery over that of intramuscular and subcutaneous delivery is clearly stated at 29:3-9. D'Antonio also states that his invention concerns hypodermic fluid injections for medical treatment for a patient 1:15-17, 22:11-20 (i.e., drug administration). D'Antonio and Puri are cited to show the prior art recognition that delivery to the ID compartment gives a greater Cmax than SC delivery as suggested in the results that a lower dose of drug can be used with ID delivery as compared to SC delivery.

Applicant argues that Ganderton does not have the correct configuration to deliver to the ID compartment because the device would act like a "bed of nails" and the application of pressure would not result in delivery to the ID compartment. This argument is not convincing because Ganderton is relied upon for teaching delivery with multiple needles and the use of zero exposed height (see rejections above). Whether Ganderton would require a higher pressure with multiple needles than would be required with a single needle is not relevant. Additionally, applicant has not recited nor disclosed any particular pressure range required to achieve the claimed method.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Hayes at (571) 272-4959. The examiner can usually be reached Monday -Thursday, 7:00-4:30, and on alternate Fridays. The fax number for submitting official papers is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

mjh
20 February 2006

MICHAEL J. HAYES
PRIMARY EXAMINER